Supreme Court, U.S.
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No. 97-1265

In the

# Supreme Court of the United States

OCTOBER TERM, 1997

In re: SOFAMOR DANEK GROUP, INC.,

BRUCE G. MURPHY, RANDY OWEN,
MARY KENNEDY and LYNDA KRAMER

*Petitioners,*

- against -

SOFAMOR DANEK GROUP, INC., ET AL.,

*Respondents.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR
THE SIXTH CIRCUIT

## RESPONDENTS' BRIEF IN OPPOSITION

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## QUESTIONS PRESENTED

**1.** Should a writ of certiorari be denied where Petitioners assert only fact-specific disputes or the misapplication of a properly stated rule of law in challenging the correctness of the opinions below, which dismissed this action on the ground that Sofamor Danek Group, Inc. ("SDG") accurately disclosed all material information concerning its financial status, including extensive disclosures in its public filings?

**2.** Does the precedent of *Basic Inc. v. Levinson*, 485 U.S. 224 (1988) and *Chiarella v. United States*, 445 U.S. 222 (1980) demonstrate that, where a company's omissions under the federal securities laws are not material or plaintiffs fail to establish that the company has a duty to disclose the omitted information, the omissions — whether of specific promotional information or "hard" facts — are not actionable?

## RULE 29.6 STATEMENT

Sofamor Danek Group, Inc. has no parent company. It has three nonwholly owned subsidiaries:

Danek Korea Co., Ltd.
Somepic Technologie S.A.
Kobayashi Sofamor Danek K.K.

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## RESPONDENTS' BRIEF IN OPPOSITION

### STATEMENT OF THE CASE

Substituting overheated rhetoric for legal argument, Petitioners seriously mischaracterize the proceedings below. Their shareholder strike suit was properly dismissed with prejudice by the United States District Court for the Western District of Tennessee, and the dismissal was properly affirmed by the United States Court of Appeals for the Sixth Circuit. Both courts determined, in accordance with well-established and uncontroversial precedent, that Petitioners

failed to allege a single legally cognizable untrue statement or relevant omission under Rule 10b-5.

**Overview**

Sofamor Danek Group, Inc. ("SDG") is a publicly traded company incorporated in Indiana and headquartered in Memphis, Tennessee. Its principal focus is the development, preparation and distribution of prescription spinal fixation instrumentation systems throughout the United States and worldwide. These multiple-component products are used as "surgical splints" to stabilize the spine and promote successful fusion of vertebrae after spinal surgery.

This lawsuit was filed after SDG was named as a defendant in a series of product liability actions premised on the claim that SDG and other spinal implant manufacturers improperly promoted their products for off-label use in violation of FDA requirements. Petitioners copied the claims of the products liability plaintiffs and asserted that SDG's failure to admit in its public filings that it had in fact violated FDA regulations constituted securities fraud.

SDG has vigorously defended the products liability litigation. The company believes that it has complied with all applicable FDA regulations. SDG made substantial and complete disclosures concerning the status of its products with the FDA and concerning issues relating to the promotion of its products, the subject matter of plaintiffs' alleged "omissions" and "affirmative misrepresentations." Indeed, more than four years after the commencement of the products liability lawsuits and nationwide publicity concerning "pedicle fixation," and unprecedented efforts by the lawyers who aggregated the product claims, the FDA has not charged SDG with any improper action and no court has held that SDG violated in any way an FDA regulation. With the passage of time, it has become evident that the "disclosures" and "omissions" on which this suit is premised

are not only wrong, but had they been made would have been disastrous to the company's shareholders, who are purportedly represented by these Petitioners.

Each of SDG's spinal instrumentation systems has been cleared for promotion and sale by the FDA. *See* R. 28, Danek 1992 Form 10-K, dated March 29, 1993, p. 5; R. 28, Danek 1993 Form 10-K, dated March 30, 1994, pp. 6-7. Among the components in SDG's systems are screws which have been cleared by the FDA for certain uses. However, SDG may not promote these screws for other uses. Until early 1995, screws could not be labeled or promoted for use in the pedicles (bony support structures) of the cervical, thoracic or lumbar spine. SDG was permitted to promote the screws for use by a surgeon in the vertebral body via an anterior surgical approach and in the sacrum.

Many physicians utilize the screws for pedicle fixation. Under the "practice of medicine" exception, or "medical judgment" rule[1], SDG is legally permitted to sell its spinal fixation devices to physicians who may choose to employ

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[1] Petitioners' characterization of the "medical judgment" rule as an "apparent loophole," Petition at 7, is egregiously misleading. As courts have long recognized, the "medical judgment" rule constitutes long-standing FDA policy, which permits physicians to offer their patients state-of-the-art treatment. *See, e.g., United States v. Evers*, 643 F.2d 1043, 1048 (5th Cir. 1981) (citing FDCA legislative history and FDA rulemaking interpreting the "practice of medicine" exception); *United States v. Algon Chem., Inc.*, 879 F.2d 1154, 1163 (3d Cir. 1989) ("Congress would have created havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming procedure of obtaining FDA approval before putting drugs to new uses. Thus Congress exempted the practice of medicine from the [Food Drug and Cosmetic] Act so as not to limit a physician's ability to treat his patients") (citations omitted). *See also Femrite v. Abbott Northwestern Hosp.*, 568 N.W.2d 535, 541-42 (Minn. Ct. App. 1997) (after considering FDA documents, court concluded that physicians' implantation of bone screws in the vertebral pedicles "was a permissible 'off-label' use" not in violation of FDA regulations).

pedicle fixation techniques. However, FDA regulations restrict activities that the agency considers advertisement, labelling, promotion or marketing of devices for that purpose. Petitioners' complaint discloses that on July 22, 1994, an FDA advisory panel issued an unanimous recommendation which would permit manufacturer labelling and promotion of screws in the pedicle of the spine for certain medical indications. This recommendation was based on clear evidence of safety and efficacy. F-43-44, Complaint ¶ 95.[2]

**Petitioners' Claims and SDG's Disclosures**

Petitioners filed suit on April 25, 1994, purporting to represent a class of persons who purchased the common stock of SDG, or its predecessor Danek Group, Inc., from February 8, 1993 through and including April 21, 1994. F-10-11, Complaint ¶ 23. The essence of Petitioners' claims against SDG and the individual defendants[3] was that they had failed to disclose that the growth in revenues and profits was

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[2] After the filing of the complaint, SDG received approval for promotion of screws for use in the lumbar pedicles for a variety of medical indications. *See* Orthopedic Devices: Classification, Reclassification, and Codification of Pedicle Screw Spinal Systems, 60 Fed. Reg. 51,946 (Oct. 4, 1995) (citing SDG's Section 510(k) application dated December 22, 1994). These FDA approvals included Section 510(k) clearance letters for SDG nonanterior hook and rod or plate and screw spinal instrumentation systems, received on the following dates: January 20, 1995 (TSRH system); August 7, 1995 (TSRH system); August 14, 1995 (Dyna Lok system); August 25, 1995 (Paragon system); August 28, 1995 (GDLH system); October 30, 1995 (Dyna Lok system); January 30, 1996 (TSRH and GDLH systems); February 9, 1996 (CD Liberty system); February 14, 1996 (Augment-T and CD Horizon systems); October 1, 1996 (CD system); December 5, 1996 (CD Horizon system); January 14, 1997 (Alpha system); February 6, 1997 (Titanium CD Horizon system); April 21, 1997 (Liberty system); and October 16, 1997 (CD system).

[3] The individual defendants, present or former officers and directors of Sofamor, Danek or SDG, include E. Ron Pickard ("Pickard"), Laurence Y. Fairey ("Fairey"), Leander D. Beard ("Beard"), George F. Rapp ("Rapp"), Miles D. Igo ("Igo"), and Alan J. Olsen ("Olsen").

based on illegal promotion of their products. The complaint alleges that the defendants violated sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a) (the "1934 Act"), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5 (1997), F-50-57, Complaint ¶¶ 112-122; that they negligently misrepresented certain facts, F-57-58, Complaint ¶¶ 123-126; and that they committed common law fraud and deceit, F-58-59, Complaint ¶¶ 127-129.

The district court correctly held that SDG had no duty to disclose, by way of predicting future FDA enforcement action or by pejoratively characterizing facts, what Petitioners claim was omitted from its Securities and Exchange Commission ("SEC") filings. In making this determination, the court quite properly examined SDG's public filings, which amply demonstrate that the company disclosed all of the information concerning its marketing practices and regulatory status that was required by the securities laws. The complaint itself, in contrast, indulged in selective quotation and lengthy mischaracterization of SDG's public filings[4].

The public filings show that SDG and its predecessor Danek Group, Inc. ("Danek") repeatedly made full disclosure of the regulatory status of its products. They specifically indicated the potential uncertainties associated with that status, including present and potential impacts on SDG's

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[4] Petitioners do not disagree that a court may properly consider on a motion to dismiss the full text of SEC filings mentioned in the complaint. Indeed, SDG was entitled to have a court consider the SEC filings under at least four theories, including: **(i)** public disclosure documents filed with the SEC, *see, e.g., Kramer v. Time Warner Inc.*, 937 F.2d 767, 774 (2d Cir. 1991); **(ii)** documents integral to plaintiffs' claims, *see, e.g., Cortec Indus. v. Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991), *cert. denied*, 503 U.S. 960 (1992); **(iii)** documents of which the court can take judicial notice, *see, e.g., Kramer*, 937 F.2d at 773; and **(iv)** incorporation by reference, *see, e.g., Pompano-Windy City Partners v. Bear Stearns & Co.*, 794 F. Supp. 1265, 1281 (S.D.N.Y. 1992).

promotional activities. In fact, Danek disclosed that its products were not cleared or approved for use in the pedicle area of the spine in public filings as early as May 16, 1991 — well over one year before the putative class period began and before the putative class plaintiffs purchased their shares. *See* R. 28, Danek Prospectus, dated May 16, 1991. Time and again, SDG both explained the scope and limitations of its FDA labelling approvals, and disclosed that its products were not approved for pedicular fixation labelling, but that many physicians used them for this "off label" indication, as is clearly authorized under the FDA's "practice of medicine" doctrine. SDG disclosed in detail the FDA's expressed concerns regarding improper promotion, and advised the market that were the FDA to pursue the company for any promotional violations, there would likely be adverse material effects on SDG's business.

The district court's October 3, 1995 order properly disposed of a legally deficient shareholder strike suit. It was entirely in accord with well-established legal precedent, and was affirmed by the Sixth Circuit on August 14, 1997. On October 9, 1997, after determining that the relevant issues had been "fully considered upon the original submission and decision of the case," the Sixth Circuit denied Petitioners' Petition for Rehearing and Suggestion for Rehearing *En Banc*. B-2.

Petitioners now claim, erroneously, that the lower courts "failed to in any way address the Petitioners-Plaintiffs' affirmative misrepresentation claim," Petition at 4. This "affirmative misrepresentation" claim, which is repeatedly belied by SDG's public filings, consists of two points: "First, that SDG publicly and affirmatively misrepresented to its investors and the market in general that it was not engaged in conduct or activities geared to promoting its [spinal instrumentation systems] for unapproved uses (*e.g.*, for pedicular attachment). Second, that given SDG's several and

undeniable promotional activities... these public and affirmative misrepresentations were *patently untrue*." Petition at 13. Petitioners also argue, incorrectly, that the lower courts "confused the question of whether it was necessary to disclose the material information regarding certain of the Company's activities, with the question of whether the disclosure needed to express the information in pejorative terms or to explicitly predict the potential ramifications of those activities." Petition at 5. They claim that SDG incurred a duty to disclose once it "directly addressed the issue of its promotional activities," Petition at 14, and that "the specific, concrete promotional activities SDG engaged in are facts that are at least as 'hard' as the merger negotiations activity at issue in *Basic, Inc. v. Levinson*, 485 U.S. 224 (1988)," Petition at 15.

## REASONS FOR DENYING THE WRIT

### I. A writ of certiorari should be denied where, as here, Petitioners assert only fact-specific disputes or the misapplication of a properly stated rule of law in challenging the correctness of the dismissal of this action on the ground that Sofamor Danek Group, Inc. ("SDG") accurately disclosed all material information concerning its financial status, including extensive disclosures in its public filings.

Petitioners argue erroneously that the courts below "simply ignored" their claim based on purported "affirmative misrepresentations." Petition at 12. Petitioners' point is inaccurate, and a similar argument was rejected by the Sixth Circuit in denying Petitioners' request for a rehearing *en banc*, *see* E-1, E-3-9. As the record makes clear, Petitioners'

argument concerning "affirmative misrepresentations" in no way implicates issues that warrant the granting of a writ of certiorari.

The lower courts' rulings on this matter are fully in accord with *Basic Inc. v. Levinson*, 485 U.S. 224 (1988) and *Aschinger v. Columbus Showcase Co.*, 934 F.2d 1402 (6th Cir. 1991), which recognize that under § 10(b) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder, a claim may be grounded upon an affirmative misrepresentation. As *Basic* teaches, issues of materiality are particularly case and fact specific. 485 U.S. at 238-41. The lower courts' holdings were not only well-grounded in the facts pleaded in the complaint or supplemented by the company's SEC filings, but created no conflict, far less a "direct" one, with Supreme Court or Sixth Circuit precedent.

Petitioners' principal claim in this action is that SDG committed securities fraud, by failing to disclose purported violations of FDA regulations. However, Petitioners' allegations — as the district court correctly determined when dismissing the complaint with prejudice, and as the Sixth Circuit correctly affirmed — fail to support a cause of action under the federal securities laws.

The Sixth Circuit's opinion uncontroversially interprets *Basic* and *Aschinger* as follows:

> To state a cause of action under §10(b) and Rule 10b-5 a plaintiff must plead that the defendant made a false statement or omitted to state a material fact which should have been disclosed, and that the plaintiff's reasonable reliance on the statement or omission proximately caused the plaintiff's injury. *See Aschinger v. Columbus Showcase Co.*, 934 F.2d 1402, 1409 (6th Cir. 1991). Misrepresented or omitted facts are material only if a reasonable

> investor would have viewed the misrepresentation or omission as "having significantly altered the total mix of information available." *Basic, Inc. v. Levinson*, 485 U.S. 224, 232 (1988) (internal quotation marks and citation omitted).

A-15-16 (citations omitted).

Moreover, the Sixth Circuit accurately noted, "Before liability for non-disclosure can attach, the defendant must have violated an affirmative duty of disclosure. *See Basic*, 485 U.S. at 239 n.17 ('Silence, absent a duty to disclose, is not misleading under Rule 10b-5'). Ordinarily, at least, a company is under no duty to disclose the details of its merchandising practices... Materiality alone is not sufficient to place a company under a duty of disclosure." A-16 (citations omitted).

Petitioners argue that the lower courts overlooked their claim for violation of the federal securities laws based on SDG's purportedly untrue "affirmative representations" that it "was not engaged in conduct or activities geared to promoting" its products for "unapproved uses (*e.g.*, for pedicular attachment)." *See* Petition at 13. In effect, this is just a rehash of their claim that SDG promoted its products in violation of FDA regulations. The Sixth Circuit considered at length all of plaintiffs' claims about affirmative misstatements and omissions concerning SDG's promotional practices, and correctly disposed of this claim after examining closely the relevant SEC filings. *See* A-6-7 (describing SDG's disclosures in its public filings concerning pedicular attachment, including SDG's disclosure of an August 1993 FDA warning letter concerning the practice); A-12-13 (detailed summary of plaintiffs' allegations that "the market was unaware that the company was improperly promoting its products for pedicular use"); A-14-17 (analysis of those allegations in light of

governing law, including *Basic*, with conclusion that SDG did not violate federal securities laws).

The Sixth Circuit correctly held that the sales and earnings data publicly reported by SDG "are 'hard' numbers, the accuracy of which has never been challenged by the plaintiffs." A-19. The Sixth Circuit also observed, "Neither have the plaintiffs pointed to any affirmative misstatement in the company's explanations of the numbers." *Id.* Rather, SDG repeatedly disclosed all that was required of it under the federal securities laws, and "Each of the company's 10-K forms explicitly mentioned the risk that the FDA might obtain an injunction" against distribution of its products. *Id.* at A-21.

The public filings show that SDG and its predecessor Danek repeatedly made full disclosure of the regulatory status of its products and its promotional activities. *See, e.g.*, R. 28, 1993 Danek Proxy Statement, at 61 (disclosing that "medical education, physician training and developing personal relations with surgeons are the integral components" to marketing strategy).

At least four Danek public filings disclosed that the screw components of Danek's product line were not FDA cleared or approved for pedicle use; that many surgeons legally use these screws in the pedicle; that the FDA might take action in the future that would affect such use; that the FDA was investigating improper promotional activities; and that FDA action could have a material adverse impact on Danek's business and financial conditions. *See* R. 28, Danek Prospectus, dated May 16, 1991; R. 28, 1992 Form 10-K; R. 28, 1993 Form 10-K; A-20. As the Sixth Circuit opinion recites, "In August of 1993, as the company disclosed in its Form 10-K for that year, 'Danek and six other companies received warning letters from the FDA, primarily regarding the issue of supporting medical education programs that

actually 'demonstrate' the use of screws in the pedicle of the spine'." A-8.

Thus, SDG disclosed all that was required by the federal securities laws concerning its marketing practices and regulatory status, and in making those disclosures, it asserted nothing that could be legally or logically construed as an "affirmative false statement." The Sixth Circuit concluded that no more was required of SDG under the federal securities laws. That conclusion is well reasoned and fully in accord with Supreme Court and Sixth Circuit precedent on the duty of disclosure, including *Basic* and *Aschinger*.

The Sixth Circuit's opinion with respect to the adequacy and accuracy of SDG's disclosures was solidly grounded upon the reasoning of the trial court. As that court stated, to be actionable under the securities laws, a complaint must point to some affirmative statement that was false or misleading when made or as to which prompt correction was "'necessary to make' that affirmative statement 'not misleading.'" C-14; 17 C.F.R. § 240.10b-5 (1997). After examining the full documents that were selectively quoted by plaintiffs, the trial court properly found that none of SDG's affirmative statements were actionable. C-21.

In sum, Petitioners complain not so much that the lower courts departed from established precedent, but rather that the facts of this case should have led to a different result. Petitioners' argument falls squarely within the Court's guidance that, "A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." Supreme Court Rule 10. Whether or not SDG should have disclosed additional facts about how it marketed its products does not involve issues of precedent-setting importance, and Petitioners fail to show "compelling reasons," *id.*, to support such a grant.

## II. The well-established precedent of *Basic Inc. v. Levinson*, 485 U.S. 224 (1988) and *Chiarella v. United States*, 445 U.S. 222 (1980) demonstrates that, where a company's omissions under the federal securities laws are not material or plaintiffs fail to establish that the company has a duty to disclose the omitted information, the omissions — whether of specific promotional information or "hard" facts — are not actionable.

Petitioners argue, in addition, that the lower courts "erred in their application of the relevant law" in determining that SDG had no duty to disclose further information about its promotional activities. Petition at 14. Specifically, Petitioners claim that SDG was required to disclose more about its activities once it "took it upon itself to speak at all," Petition at 15, and that SDG was required to disclose such matters because they constituted "cold, *hard* facts" concerning purportedly material activities. Petition at 15-16.

This argument also fails utterly to warrant the Court's granting of the Petition. Not only is a petition for a writ of certiorari "rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law," Supreme Court Rule 10, but both lower courts were plainly correct in their application of the relevant law.

Indeed, with respect to this point, both the Sixth Circuit and the district court followed the governing standard that has long been established by this Court under *Basic*.[5]

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[5] The Sixth Circuit noted, "We find ourselves in substantial agreement with the district court's analysis," A-3, and indicated that its ruling was "for substantially all of the reasons given by Judge Turner," A-28.

Contrary to plaintiffs' assertions, additional information about specific promotional activities and "hard" facts is neither material nor subject to required disclosure under the *Basic* standard. The district court opinion noted, "[i]nvestors, of course, would like to have any material information, but they are not entitled to all information that might somehow be of assistance to them in predicting the future of the stock." C-16. That court cites *Basic* and *Chiarella* for the well-established proposition that omissions are only actionable where defendants have a "duty to disclose" the information at issue. C-17. However, contrary to *Basic*, the Petition now argues for what is really "all information that might somehow be of assistance" to shareholders, as distinct from material information that is required to be disclosed. C-16.

The courts below did not determine that any of SDG's purported omissions were material, but held that even if they were, plaintiffs had failed to satisfy the "duty to disclose" requirement which is a prerequisite to any securities fraud claim. That reasoning applies equally to the "specific" and "hard fact" categories of information cited in the Petition. With respect to all of SDG's alleged omissions, the admittedly true statements made and reports filed by SDG cannot be shown to have been misleading by reason of SDG's failure to disclose the areas of information alleged in the Complaint to be missing. C-28-29. There is simply no such duty under the federal securities laws.

The district court and the Sixth Circuit both held that, even if materiality is established, a duty to disclose the information arises only under specific circumstances, namely: **(i)** where a corporate insider uses material non-public information to profit financially in the securities markets; **(ii)** where a company omits material information in a report it must file pursuant to a particular statute or regulation; or **(iii)** where defendants have made a public statement, and further disclosures are necessary to make the statement not

misleading. C-18 (citing *Chiarella*, 445 U.S. at 226-30; *Roeder v. Alpha Indus.*, 814 F.2d 22, 26-27 (1st Cir. 1987); *Howing Co. v. Nationwide Corp.*, 826 F.2d 1470, 1481 (6th Cir. 1987), *cert. denied*, 486 U.S. 1059 (1988)); Opinion at 11-12. Petitioners have failed to demonstrate that any of these circumstances apply to SDG's purported omissions, and have therefore failed to establish any claim against SDG under the federal securities laws.

For all of these reasons, the Sixth Circuit's affirmation of the district court's dismissal properly disposed of a legally deficient shareholder strike suit. Both opinions are uncontroversial and fully in accordance with existing Supreme Court and Sixth Circuit precedent, including *Basic* and *Aschinger*.[6] In no way do the perfunctory, fact-specific arguments set forth in the Petition warrant this Court's utilization of its resources in further reviewing Petitioners' groundless claims.

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[6] Notably, Petitioners, who discuss *Aschinger* at length in their Sixth Circuit Petition for Rehearing and Suggestion for Rehearing *En Banc*, E-1 *et seq.*, do not even attempt to argue to this Court that the Sixth Circuit's present opinion conflicts with the precedent set forth in *Aschinger*.

## CONCLUSION

For all of the foregoing reasons, SDG respectfully requests that this Court deny the Petition for a Writ of Certiorari.

Dated: April 3, 1998

Respectfully submitted,

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